



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 16

[Docket Nos. FDA-2011-N-0143 and FDA-2011-N-0146]

Food and Drug Administration Food Safety Modernization Act: Proposed Rules on Foreign Supplier Verification Programs and the Accreditation of Third-Party Auditors/Certification Bodies; Public Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public meetings.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing two public meetings to discuss two proposed rules aimed at strengthening assurances that imported food meets the same safety standards as food produced domestically. The Foreign Supplier Verification Programs (FSVP) proposal establishes requirements for importers to verify that their foreign suppliers are implementing the modern, prevention-oriented food safety practices called for by the Food Safety Modernization Act (FSMA) and achieving the same level of food safety as domestic growers and processors. The second proposed rule on the Accreditation of Third-Party Auditors/Certification Bodies would strengthen the quality, objectivity, and transparency of foreign food safety audits on which many U.S. food companies and importers currently rely to help manage the safety of their global food supply chains. The purpose of these public meetings is to solicit oral stakeholder and public comments on the proposed rules and to inform the public about the rulemaking process (including how to submit comments, data, and other information to the rulemaking dockets), and to respond to questions about the proposed rules.

DATES: See section II, “How to Participate in the Public Meeting” in the SUPPLEMENTARY INFORMATION section of this document for date and time of the public meetings, closing dates for advance registration, and information on deadlines for submitting either electronic or written comments to FDA’s Division of Dockets Management.

ADDRESSES: See section II, “How to Participate in the Public Meeting” in the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT:

For questions about registering for the meetings, to register by phone, or to submit a notice of participation by mail, FAX, or email: Lauren Montgomery, Teya Technologies, LLC, 101 East 9th Ave., Suite 9B, Anchorage, Alaska 99501, 443-833-4297, FAX: 907-562-5497, email: lauren.montgomery@teyatech.com.

For general questions about the meetings, to request an opportunity to make an oral presentation at the public meetings, to submit the full text, comprehensive outline, or summary of an oral presentation, or for special accommodations due to a disability, contact: Juanita Yates, Center for Food Safety and Applied Nutrition (HFS-009), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1731, email: juanita.yates@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FSMA (Public Law 111-353), was signed into law by President Obama on January 4, 2011, to better protect public health by helping to ensure the safety and security of the food supply. FSMA amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish the foundation of a modernized, prevention-based food safety system. Among other things,

FSMA requires FDA to issue regulations requiring preventive controls for human food and animal food, set standards for produce safety, and require importers to have a program to verify that the food products they bring into the United States are produced in a manner consistent with U.S. standards.

FSMA was the first major legislative reform of FDA's food safety authorities in more than 70 years, even though FDA has increased the focus of its food safety efforts on prevention for more than a decade. In the Federal Register of January 16, 2013 (78 FR 3504 and 78 FR 3646), FDA announced the establishment of two dockets so that the public can review the produce safety proposed rule and the preventive controls proposed rule for human food and submit comments to the Agency. These proposed rulemakings were the first of several key proposals in furtherance of FSMA's food safety mandate. For information on the produce safety proposed rule, the preventive controls rule, and related fact sheets, see FDA's FSMA Web page located at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>.

In the Federal Register of July 29, 2013 (78 FR 45730 and 78 FR 45782), FDA announced the second set of FSMA proposed rules and the establishment of two additional dockets so that the public can review the proposals on FSVP and the Accreditation of Third-Party Auditors/Certification Bodies and submit comments to the Agency. Under the proposed FSVP rule, those importing FDA-regulated food into the United States will be held accountable for verifying that their suppliers produce food in a manner consistent with U.S. standards. Under the proposed rule that would establish the Accreditation of Third-Party Auditors/Certification Bodies program, the FDA would recognize accreditation bodies based on certain criteria such as competency and impartiality. The accreditation bodies, which could be foreign governments or

their agencies or private companies, would in turn accredit third-party auditors to audit and issue certifications for foreign food facilities and food.

FDA is announcing a series of public meetings entitled “The Food Safety Modernization Act Public Meetings on Proposed Rules for Foreign Supplier Verification Programs (FSVP) and for the Accreditation of Third-Party Auditors/Certification Bodies for Imported Food” so that the food industry, consumers, foreign governments, and other stakeholders can better evaluate and comment on the proposals. These meetings, following the Washington, DC public event on September 19 and 20, 2013, are the final two meetings FDA plans to hold during the proposed rules’ comment period. All three public meetings will have the same agenda and are intended to facilitate and support the proposed rules’ evaluation and commenting process.

II. How to Participate in the Public Meetings

FDA is holding the public meetings on the FSVP and the Accreditation of Third-Party Auditors/Certification Bodies proposed rules to inform the public about the rulemaking process, including how to submit comments, data, and other information to the rulemaking docket; to respond to questions about the proposed rules; and to provide an opportunity for interested persons to make oral presentations. Due to limited space and time, FDA encourages all persons who wish to attend the meetings to register in advance. There is no fee to register for the public meetings, and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited. Onsite registration will be accepted, as space permits, after all preregistered attendees are seated.

Those requesting an opportunity to make an oral presentation during the time allotted for public comment at the meeting are asked to submit a request and to provide the specific topic or issue to be addressed. Due to the anticipated high level of interest in presenting public comment

and limited time available, FDA is allocating 3 minutes to each speaker to make an oral presentation. Speakers will be limited to making oral remarks; there will not be an opportunity to display materials such as slide shows, videos, or other media during the meeting. If time permits, individuals or organizations that did not register in advance may be granted the opportunity to make an oral presentation. FDA would like to maximize the number of individuals who make a presentation at the meeting and will do our best to accommodate all persons who wish to make a presentation or express their opinions at the meeting.

FDA encourages persons and groups who have similar interests to consolidate their information for presentation by a single representative. After reviewing the presentation requests, FDA will notify each participant before the meeting of the approximate time their presentation is scheduled to begin, and remind them of the presentation format (i.e., 3-minute oral presentation without visual media).

While oral presentations from specific individuals and organizations will be necessarily limited due to time constraints during the public meeting, stakeholders may submit electronic or written comments discussing any issues of concern to the administrative record (the docket) for the rulemaking. All relevant data and documentation should be submitted with the comments to the relevant docket i.e., FSVP, Docket No. FDA-2011-N-0143, or accreditation of third-party auditors, Docket No. FDA-2011-N-0146.

Table 1 of this document provides information on participation in the public meetings:

Table 1.--Information on Participation in the Meetings and on Submitting Comments to the Rulemaking Dockets

	Date	Electronic Address	Address	Other Information
Public meeting	October 10, 2013, from 8:30 a.m. to 5 p.m. and October 11, 2013, from 8:30 a.m. to 12:30 p.m.		Hyatt Regency Miami 400 SE Second Ave. Miami, FL 33131	Onsite registration both days from 8: a.m. – 8:30 a.m.
Advance registration	by October 1, 2013	Individuals who wish to participate in person are asked to preregister at http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm	We encourage you to use electronic registration if possible. ¹	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.
Request to make a Public Comment	by September 24, 2013	http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm ²		Requests made on the day of the meeting to make an oral presentation will be granted as time permits. Information on requests to make an oral presentation may be posted without change to http://www.regulations.gov , including any personal information provided.
Request special accommodations due to a disability	by September 24, 2013	Juanita Yates, email: juanita.yates@fda.hhs.gov	See FOR FURTHER INFORMATION CONTACT	
Submit electronic or written comments	November 26, 2013	Docket Nos. FDA-2011-N-0143 and FDA-2011-N-0146		

¹ You may also register via email, mail, or FAX. Please include your name, title, firm name, address, and phone and FAX numbers in your registration information and send to: Lauren Montgomery, Teya Technologies, LLC, 101 East 9th Ave., Suite 9B, Anchorage, Alaska 99501, 443-833-4297, FAX: 907-562-5497, email: lauren.montgomery@teyatech.com. Onsite registration will also be available.

² You may also request to make an oral presentation at the public meeting via email. Please include your name, title, firm name, address, and phone and FAX numbers as well as the full text, comprehensive outline, or summary of your oral presentation and send to: Juanita Yates, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1731, email: juanita.yates@fda.hhs.gov.

Table 1.--Information on Participation in the Meetings and on Submitting Comments to the Rulemaking Dockets

	Date	Electronic Address	Address	Other Information
Public meeting	October 22, 2013, from 8:30 a.m. to 5 p.m. and October 23, 2013, from 8:30 a.m. to 12:30 p.m.		Hilton Long Beach & Executive Meeting Center 701 West Ocean Blvd. Long Beach, CA 90831	Onsite registration both days from 8 a.m. – 8:30 a.m.
Advance registration	by October 8, 2013	Individuals who wish to participate in person are asked to preregister at http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm	We encourage you to use electronic registration if possible. ¹	There is no registration fee for the public meetings. Early registration is recommended because seating is limited.
Request to make a Public Comment	by October 1, 2013	http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm ²		Requests made on the day of the meeting to make an oral presentation will be granted as time permits. Information on requests to make an oral presentation may be posted without change to http://www.regulations.gov , including any personal information provided.
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III. Comments, Transcripts, and Recorded Video

Information and data submitted voluntarily to FDA during the public meeting will become part of the administrative record for the relevant rulemaking and will be accessible to the public at <http://www.regulations.gov>. The transcript of the proceedings from the public meeting will become part of the administrative record for each of the rulemakings. Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov> and at FDA's FSMA Web site at: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>. It may also be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: September 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.